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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,093	01/29/2004	Scott Ciarrocca	GYN-5010	4606
27777	7590	01/12/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/767,093	Applicant(s) CIARROCCA, SCOTT	
	Examiner Alex B. Toy	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-14 is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8, 15-18 and 20 is/are rejected.
- 7) ☒ Claim(s) 4-6 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/18/04; 5/27/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (U.S. Pat. No. 6,071,274).

Regarding claim 1, Thompson discloses a bipolar electrosurgical instrument comprising:

an introducer 10 having a handle portion 18 and an outer shaft 26 coupled to the handle portion, the introducer having a channel extending therein from an opening 40 at a distal end of the introducer (Fig. 1);

a snare 20 slidably positionable within the channel and slidable between an undeployed position (Figs. 1 and 2A) wherein it is substantially retracted within the channel and a deployed position (Fig. 3A) wherein a distal portion of the snare extends

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outwardly from the channel, wherein at least the distal portion of the snare is insulated substantially along its length except for a predetermined exposed section (Figs. 2A);

a first electrically conductive member 28 for coupling with a source of RF energy, the first electrically conductive member being positioned within the snare and having an active electrode exposed through the predetermined exposed section 40 of the snare;

a second electrically conductive member 28 for coupling with a grounding element, the second electrically conductive member being positioned within the snare and having a return electrode portion exposed through the predetermined exposed section of the snare (col. 37, ln. 37-39);

a retention element at a distal end of the snare for securing the distal end of the snare to the introducer to thereby form a looped configuration of the snare (col. 9, ln. 50-52 and Fig. 3A); and

at least one fluid delivery channel extending through the introducer between a fluid inlet at the proximal end of the introducer and a fluid outlet at the distal end of the introducer that is located in proximity to the exposed section of the snare (col. 9, ln. 53-58).

Regarding claim 8, Thompson discloses the instrument according to claim 1, wherein the predetermined exposed section is on one side of the snare (Fig. 2A).

Regarding claim 15, Thompson discloses a bipolar electrosurgical instrument comprising:

an introducer having a channel therein extending from an opening 40 at a distal end thereof (Fig. 1);

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an electrically conductive snare 20 slidably positioned within the channel and slidable between an undeployed position (Figs. 1 and 2A) wherein it is substantially retracted within the channel and a deployed position (Fig. 3A) wherein a distal portion of the snare extends outwardly from the channel, the electrically conductive snare being substantially insulated but for a predetermined exposed section 40, and having an active 28 and a return 28 electrode exposed through said exposed section (col. 37, ln. 37-39);

a retention element at a distal end of the snare for securing the distal end of the snare to the introducer to thereby form a looped configuration of the snare (col. 9, ln. 50-52 and Fig. 3A); and

at least one fluid delivery channel extending through the introducer between a fluid inlet and a fluid outlet at the distal end of the introducer and located in proximity to the exposed section of the snare (col. 9, ln. 53-58).

Regarding claim 16, Thompson discloses the instrument according to claim 15, wherein the introducer 10 further includes a handle portion 18 and an outer shaft 26 adjacent to and extending from the handle portion (Fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg (U.S. Pat. No. 6,527,769 B2) in view of Thompson ('274).

Regarding claim 1, Langberg discloses an electrosurgical instrument comprising:
an introducer having an outer shaft with a channel extending therein from an opening at a distal end of the introducer (Fig. 8A);

a snare 814 slidably positionable (col. 20, ln. 39-41) within the channel and slidable between an undeployed position (not shown) wherein it is substantially retracted within the channel and a deployed position (Fig. 8A) wherein a distal portion of the snare extends outwardly from the channel, wherein at least the distal portion of the snare is insulated substantially along its length except for a predetermined exposed section (814);

a first electrically conductive member for coupling with a source of RF energy (col. 9, ln. 23-27), the first electrically conductive member being positioned within the snare 814 and having an active electrode exposed through the predetermined exposed section of the snare (Fig. 8A); and

a retention element 812 at a distal end of the snare for securing the distal end of the snare to the introducer to thereby form a looped configuration of the snare (Fig. 8A).

The claim differs from Langberg in calling for the instrument to have a handle with the outer shaft coupled to the handle. Langberg is silent on the presence of a handle. However, the presence of a handle is obvious, if not inherent, in view of the teaching of a handle 18 (Fig. 1) in Thompson in order to control the snare deployment and shape.

The claim also differs from Langberg in calling for the instrument to be bipolar with a second return electrode in the snare. Langberg discloses multiple electrode elements 814 (Fig. 8A) but is silent on whether the instrument is bipolar. Thompson, however, teaches a bipolar electrosurgical snare with a second electrically conductive member 28 for coupling with a grounding element, the second electrically conductive member being positioned within the snare and having a return electrode portion exposed through the predetermined exposed section of the snare (col. 37, ln. 37-39 and Fig. 3A). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the instrument of Langberg bipolar as claimed in view of the teaching of Thompson as an obvious way of operating an RF electrode instrument that is common in the art.

The claim further differs from Langberg in calling for a fluid delivery channel. Thompson, however, teaches at least one fluid delivery channel extending through the introducer between a fluid inlet at the proximal end of the introducer and a fluid outlet at the distal end of the introducer that is located in proximity to the exposed section of the

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snare (col. 9, ln. 53-58) in order to establish ionic transport of ablation energy through the fluid to tissue outside the electrode body (col. 38, ln. 28-38). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the instrument of Langberg comprise a fluid delivery channel as claimed in view of the teaching of Thompson in order to establish ionic transport of ablation energy through the fluid to tissue outside the electrode body.

Regarding claim 2, Langberg discloses the instrument according to claim 1 in view of Thompson. In addition, Langberg discloses the instrument further comprising an inner shaft 810 positioned substantially concentrically and within the outer shaft, the inner shaft having a channel extending therethrough, and the snare 814 being positionable within the inner shaft channel, and the outer and inner shafts are inherently capable of being rotated relative to one another. Furthermore, rotation of the outer and inner shafts relative to one another is obvious, if not inherent, in view of the teaching of Thompson in order to place the electrode elements of the snare in a different orientation for tissue contact (col. 10, ln. 25-31 and Fig. 4A).

Regarding claim 3, Langberg discloses the instrument according to claims 1 and 2 in view of Thompson. In addition, Langberg discloses the instrument wherein the outer shaft has a first aperture (the distal opening) and the inner shaft has a second aperture (the distal opening) therein (Fig. 8A).

Regarding claims 15 and 16, see the preceding rejection of claim 1 under 103(a).

Regarding claim 17, see the preceding rejection of claim 2 under 103(a).

Regarding claim 18, see the preceding rejections of claims 2 and 3 under 103(a). the two apertures, or distal openings, are inherently capable of being moved and aligned as claimed.

Claims 7 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson ('274) in view of Schaer (U.S. Pat. No. 5,863,291).

Regarding claim 7, Thompson discloses the instrument according to claim 1 with a fluid delivery channel. The claim differs from Thompson in calling for at least one fluid delivery channel to extend through the snare and be exposed at the predetermined exposed section of the snare. Schaer, however, teaches an instrument wherein the fluid delivery channel extends through the snare and is exposed at the predetermined exposed section of the snare to allow the fluid to cool the electrodes and the treatment area (col. 6, ln. 29-34 and Fig. 15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the fluid delivery channel of Thompson extend through the snare and be exposed at the predetermined exposed section of the snare in view of the teaching of Schaer to allow the fluid to cool the electrodes and the treatment area.

Regarding claim 20, see the rejections of claims 7 and 15.

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Allowable Subject Matter

Claims 4-6 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9-14 are allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 3910279 A	USPAT	Okada; Takeshi et al.
US 5730127 A	USPAT	Avitall; Boaz
US 6106522 A	USPAT	Fleischman; Sidney D. et al.
US 6314963 B1	USPAT	Vaska; Matthias et al.
US 6514248 B1	USPAT	Eggers; Philip E. et al.
US 6540742 B1	USPAT	Thomas; Stuart et al.
US 6733496 B2	USPAT	Sharkey; Hugh et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT *AT*
1/6/06

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER